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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,933	08/13/2001	Pierre Leroy	032751-066	6916

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EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT

PAPER NUMBER

1632

12

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/927,933

Applicant(s)
Leroy et al.

Examiner
Scott D. Priebe, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 Aug. 2001 and 13 Dec. 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-58 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 40-58 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The amendments filed 8/13/01 and 12/13/01 have been entered.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 35 and 36 filed 8/13/01 have been renumbered as claims 38 and 39. Misnumbered claims 37-55 filed 12/13/01 have been renumbered as claims 40-58. Applicant should review the claims and correct recitation of claim dependency accordingly to avoid potential rejections under 35 USC 112, 2nd para. For the purposes of restriction, the claim dependency was assumed to refer to the claim numbers as filed in the amendment of 12/13/01, rather than to the renumbered claims.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 40-42, 44-48, 51-58, drawn to an adenoviral vector encoding a ribonuclease fused to an antibody, classified in class 435, subclass 320.1.
- II. Claims 40-42, 44-48, 51-58, drawn to an adenoviral vector encoding diphtheria toxin fused to an antibody, classified in class 435, subclass 320.1.

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- III. Claims 40-42, 44-48, 51-58, drawn to an adenoviral vector encoding cholera toxin fused to an antibody, classified in class 435, subclass 320.1.
- IV. Claims 40-42, 44-48, 51-58, drawn to an adenoviral vector encoding *Pseudomonas* exotoxin fused to an antibody, classified in class 435, subclass 320.1.
- V. Claims 40-42, 44-48, 51-58, drawn to an adenoviral vector encoding HSV thymidine kinase fused to an antibody, classified in class 435, subclass 320.1.
- VI. Claims 40-42, 44-48, 51-58, drawn to an adenoviral vector encoding a cytosine deaminase fused to an antibody, classified in class 435, subclass 320.1.
- VII. Claims 40, 41, 43-49, 51-58, drawn to an adenoviral vector encoding an immunopotentiating substance fused to an antibody, classified in class 435, subclass 320.1.
- VIII. Claims 40, 41, 44-48, 50-58, drawn to an adenoviral vector encoding signal sequence and extracellular domains I and II of CD4 protein fused to an antibody in turn fused to mature human angiogenin, classified in class 435, subclass 320.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are each drawn to different products by virtue of the gene product encoded wherein

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the active agent of the protein, e.g. cholera toxin, HSV tk, CD4 protein, do not share a common core structure or function. Consequently, each has a different mode of operation and different effect.

Inventions VIII and inventions I and VII are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination is limited to the ribonuclease human angiogenin and the immunopotentiating substance extracellular domains of CD4 protein, whereas invention I includes other ribonucleases and invention VII includes other immunopotentiating substances. The subcombinations of inventions I and VII have separate utility in that they are not required to contain an immunopotentiating substance or ribonuclease, respectively. Also, invention I can be practiced using a ribonuclease other than that required by the combination; and invention VII can be practiced using an immunopotentiating substance other than that required by the combination.

Because these inventions are distinct for the reasons given above and the search required for each group is not required for the other groups, and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Claims 40, 41, 44-48, and 51-58 link(s) inventions I-VIII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 40, 41, 44-48, and 51-58. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Furthermore, if Group I is elected, claims 40, 41, 44-48, 51-58 are generic to a plurality of disclosed patentably distinct species comprising colicin E6, *E. coli* cloacin, *Staphylococcus* nuclease, *Bacillus intermedius* barnase, *B. amyloliquefaciens* barnase, ricin, and human angiogenin. If Group VII is elected, claims 40, 41, 43-49, 51 and 58 are generic to a plurality of disclosed patentably distinct species comprising CD4 protein, high-affinity receptor for HIV-1 and Fc receptor for IgG. If either of Groups I or VII are elected, Applicant is also required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

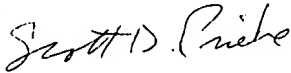
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX numbers are (703) 308-4242 or (703) 305-3014 for any type of communication. In addition, FAX numbers for a computer server system using RightFAX are also available for communications before final rejection, (703) 872-9306, and for communications after final rejection, (703) 872-9307, which will generate a return receipt. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Scott D. Priebe, Ph.D.
Primary Examiner
Technology Center 1600
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